RVD2008-16

Re-evaluation Decision

# Sodium Chlorate and Sodium Chlorite

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# Overview

## Re-evaluation Decision

After a re-evaluation of the industrial antimicrobial agents, sodium chlorate and sodium chlorite, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing sodium chlorate and sodium chlorite for sale and use in Canada.

An evaluation of available scientific information found that products containing sodium chlorate and sodium chlorite do not present unacceptable risks to human health or the environment when used according to label directions.

The regulatory approach for the re-evaluation of sodium chlorate and sodium chlorite was first presented in Proposed Re-evaluation Decision document PRVD2008-09, *Sodium Chlorate and Sodium Chlorite*, a consultation document.[1] This Re-evaluation Decision document[2] describes this stage of PMRA's regulatory process for the re-evaluation of sodium chlorate and sodium chlorite as well as summarizes the Agency's decision and the reasons for it. Appendix I summarizes the comment received during the consultation process and provides the PMRA's response to this comment. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-09.

## What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Sodium chlorate and sodium chlorite, two of the active ingredients in the current re-evaluation cycle, have been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision for uses of these active ingredients in Canada. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy).

The USEPA re-evaluated sodium chlorate and sodium chlorite and published its conclusions in two 2006 REDs.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-09, *Sodium Chlorate and Sodium Chlorite*.

## What Are Sodium Chlorate and Sodium Chlorite?

Sodium chlorate and sodium chlorite are precursors for the generation of chlorine dioxide in closed system generators. Chlorine dioxide controls slime-forming organisms in pulp and paper process waters, and in the waters of recirculating cooling towers. Factory workers may be exposed to sodium chlorite or sodium chlorate when loading these precursor chemicals into the generator for the production of chlorine dioxide.

## Health Considerations

### Can Approved Uses of Sodium Chlorate and Sodium Chlorite Affect Human Health?

**Sodium chlorate and sodium chlorite are unlikely to affect your health when used according to label directions.**

People could be exposed to sodium chlorate and sodium chlorite through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that sodium chlorate and sodium chlorite were unlikely to affect human health when used according to label directions. These conclusions apply to the Canadian situation.

#### Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest*

*Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Sodium chlorate and sodium chlorite are not currently registered in Canada for use as a pesticide on any food/feed crops but could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for sodium chlorate and sodium chlorite in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

## Environmental Considerations

### What Happens When Sodium Chlorate and Sodium Chlorite Are Introduced Into the Environment?

**Sodium chlorate and sodium chlorite are unlikely to affect non-target organisms when used according to label directions.**

In Canada, sodium chlorite and sodium chlorate are used to generate chlorine dioxide in industrial process waters. Aquatic organisms could potentially be exposed to residues (chlorite ion) of these pesticides in the effluent if it is discharged. However, the process waters or effluent must not be released into the environment without the appropriate permits. Current Canadian labels require the treatment of effluent prior to discharge. Environmental exposure is not expected from the registered use of either sodium chlorate or sodium chlorite when used according to label directions.

## Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of sodium chlorate and sodium chlorite, the PMRA is not requiring further risk-reduction measures for product labels.

## Other Information

Any person may file a notice of objection[3] regarding this decision on sodium chlorate and sodium chlorite within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[3] As per subsection 35(1) of the *Pest Control Products Act*.

# Appendix I Comments and Responses

## 1.0 Comment

There are minor typographical errors in Appendix II, PRVD2008-09.

**Response**

The errors have been corrected in the revised table. See Appendix II, RVD2008-16.

# Appendix II Toxicological Endpoints for Sodium Chlorate and Sodium Chlorite Health Risk Assessments

| Exposure Scenario (route and period of exposure) | Dose (mg/kg bw/day) | Study | Target UF/SF or MOE or $Q_1$* [a] |
|---|---|---|---|
| SODIUM CHLORATE | | | |
| Short- and intermediate-term inhalation | NOAEL = 30 mg/kg/day | Rat reproductive | 100 |
| Short- and intermediate-term incidental oral | NOAEL = 30 mg/kg/day oral | Rat sub-chronic study | 100 |
| Chronic dietary | BMDL = 0.9 mg/kg/day cRfD = 0.03 mg/kg/day | Rat chronic study | UF = 30 (3× interspecies and 10× intraspecies) |
| | cPAD = 0.03 mg/kg/day (i.e. acceptable daily intake) | | |
| SODIUM CHLORITE | | | |
| Short- and intermediate-term inhalation | NOAEL = 0.28 mg/m$^3$ | Inhalation toxicity studies in the rat | 100 |
| Short- and intermediate-term incidental oral | Oral NOAEL = 3 mg/kg/day | Two-generation reproductive toxicity study in the rat | 100 |
| Chronic dietary | Oral NOAEL = 3 mg/kg/day | Two-generation reproductive toxicity study. | 100 |
| | cPAD = 0.03 mg/kg/day (i.e. acceptable daily intake) | | |

[a] UF/SF refers to total of uncertainty and/or safety factors for dietary assessments. MOE refers to desired margin of exposure for occupational or residential assessments. $Q_1$* refers to cancer potency factor. BMDL refers to a benchmark dose analysis.